DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M2074n

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 4 1999

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Lee Doo Young
President
Du Yee Care, Inc.
#598-13, Jangkok-3ri, Jori-myun, Paju-shi
Kyungki-do, Korea

Dear Mr. Lee:

During an inspection of your firm located in Kyungki-do, Korea on March 15 - 17, 1999, our investigator determined that your firm manufactures blood lancets. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the good manufacturing practice (GMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to, where the results of a process cannot be fully verified by subsequent inspection and test, validate the process with a high degree of assurance and approve that process according to established procedures, as required by 21 CFR 820.75(a). For example, there has been no process validation of the injection molding or packaging processes.

   Your response of April 15, 1999, is not adequate. There is no documented response to the validation of the packaging processes.

2. Failure to maintain a device master record prepared, dated, and signed by a designated individual for each type of device, as required by 21 CFR 820.181. For example, each type of lancet, the Techlite and Easy-let, do not have a device master record.

   Your response of April 15, 1999, may be adequate.

3. Failure to maintain device master records, prepared and approved, including or referring to the location of device specifications, production process specifications, quality assurance procedures, or packaging and labeling

specifications, as required by 21 CFR 820.181(a), (b), (c) and (d). For example, there are no device specifications, production process specifications, quality assurance procedures or packaging and labeling specifications in the device master record.

Your response of April 15, 1999, is not adequate. Documentation for the labelling specifications and procedures are not included in the device master records provided.

4. Failure to establish and maintain procedures to control all documents that are required by this part, providing for an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part, including the date and signature of the individual(s) approving the document, and making available at all locations for which they are designated, used, or otherwise necessary, to meet the requirements of this part, as required by 21 CFR 820.40(a). For example, the "Management System Document Control" document is lacking the change request, change record forms and review for adequate and approved specifications, and the new documents created do not follow the existing procedure.

Your response of April 15, 1999, may be adequate.

5. Failure to maintain records of changes to documents including a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective, as required by 21 CFR 820.40(b). For example, new documents were created since the last inspection of July 1996, and no change records were available for review.

Your response of April 15, 1999, is not adequate. Although copies of the new change control procedure were provided, no copies of the changed documents were included. It is not possible to determine whether the new procedure is implemented.

6. Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, including provisions for handling, preservation, and storage of equipment so that its accuracy and fitness for use are maintained, as required by 21 CFR 820.72(a). For example, there are no written calibration procedures.

Your response of April 15, 1999, appears adequate. A copy of the calibration procedure was included with the response.

7. Failure to document the equipment identification, calibration dates, the individual performing each calibration, and the next calibration date, and to display on or near each piece of equipment or have readily available to the personnel using such equipment these records, as required by 21 CFR 820.72(b)(2). For example, major equipment or tools such as injection molding machines that are used to produce finished devices were not being calibrated routinely.

   Your response of April 15, 1999, appears adequate. Copies of the calibrated equipment records were included with the response.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the aware of government contracts, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the GMP requirements of the Quality System Regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report, and certification by your firm's Chief Executive Officer (CEO) (if other than yourself) that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The certification of audits should be submitted to this office by the following date:

- Initial certification by an outside consultant no later than December 10, 1999.

Given the serious nature of these violations of the Act, all devices manufactured by Du Yee Care, Inc., #598-13 Jangkok-3ri, Jori-myun, Paju-shi, Kyungki-do, Korea may be detained upon entry

into the United States (U.S.) until these violations are corrected.

In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review, and have an outside consultant certify your compliance with the Quality System Regulation no later than December 10, 1999. After we notify you that your response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations, for each violation in which the response was less than adequate. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to Carol Shirk at the above letterhead address. If you have questions or need further assistance contact Ms. Shirk by telephone at (301) 594-4595 or by FAX at (301) 594-4636.

Sincerely yours,

George Koechling for

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: Selecting a Consultant?

cc: